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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/117,357 09/22/98 STOCKEMANN

K SCH1655

HM12/0727

EXAMINER

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ART UNIT	PAPER NUMBER
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1654

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DATE MAILED:

07/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	69117,357 Examiner C. Delacroix	Stockmann et al. Group Art Unit 1654

Responsive to communication(s) filed on 1/22/98.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-9 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-9 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

**DETAILED ACTION**

The following is responsive to the Preliminary amendment received Sep. 22, 1998.

No claims are cancelled. Claims 1-9 are presented for prosecution on the merits.

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Specification***

2. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  1. Field of the Invention.
  2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

***Claim Objections***

3. Claims 1, 3, 6 and 9 are objected to because of the following informalities: in claim 1, line 3, the phrase "selected from the group of compounds Raloxifen..." is awkward. The Examiner suggests adding after "compounds" the language --consisting of-. Moreover, at line 4, "their derivatives" is not typical US claim language. The Examiner suggests using the language --derivatives thereof--.

In claim 3, line 2, the phrase "selected from the group of compounds Leuprorelin.." is also awkward. The Examiner suggests adding after "compounds", the language --consisting of-. Also in claim 3, line 4, "their derivatives" is not typical US claim language. The Examiner suggests using the language --derivatives thereof-. Moreover, in claim 3, line 2, "Centrorelax" should read --Cetrorelax-. In claims 1 and 6, "Raloxifen" and "Droloxifen" should read --Raloxifene-- and Droloxifene-. Finally, in claim 9, line 2, "used" should be substituted with --administered-. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

4. Claims 1-9 provide for the use of LHRH analogs and an anti-estrogen compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claims 1 and 3 are vague and indefinite because at lines 3-4 and lines 2-4, respectively, the phrase "selected from the group.....or...." is improper Markush terminology. Accordingly the metes and bounds of the claims are unclear. Please refer to MPEP 2173.05(h).

Additionally in claim 1, the term "especially", in line 5, renders the claim indefinite because said term links a narrower range to a broader range. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by other linking terms "such as", "for example" and "particularly" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "treatment of gynecological conditions", and the claim also recites "treatment of endometrioses and myomas" which is the narrower statement of the range/limitation. Finally, claims 1 and 3 recite the term "derivatives"; however, Applicant has not defined in the specification what is meant by "derivatives". The scope of said term is unclear.

Claim 5 is indefinite because it is not clear to the Examiner what is meant by the term "non-peptidergic". Does Applicant mean to set forth that the claimed LHRH agonist or antagonist is a non-peptide compound?

Claim 6 is vague because of the use of the term "type". The courts have held that "the word 'type', when appended to an otherwise definite term, may render said term indefinite". Please see Ex parte Copenhaver, 109 USPQ 118 (BPAI). It is unclear to the Examiner what "Raloxifen-type" means.

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Claims 7 and 8 recite the limitation "the two active ingredients" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Moreover, in claim 8, lines 1-2, the limitation "where the two active ingredients are present in common forms" is vague. What is meant by "common forms"? Does Applicant intend to set forth the limitation that the LHRH analogs and anti-estrogens are formulated together? The language "formulated together" appears to be used in the specification. The claim should be amended accordingly.

7. Presentation of claims in the form of a method of treating gynecological disorders selected from the group consisting of endometriosis and myomas would be allowable.

#### ***Conclusion***

Hence, claims 1-9 are rejected.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dodge 5,451,590 see col. 2, lines 45-50; col. 4, lines 55-57.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward PhD, can be reached on (703) 308-4028. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM



July 15, 1999

*M.P.W.*  
MICHAEL P. WOODWARD  
PRIMARY EXAMINER  
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